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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,388	07/20/2001	Lawrence L. Kunz	295.003US5	1690

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EXAMINER	
ROBINSON, HOPE A	
ART UNIT	**PAPER NUMBER**
1652	
MAIL DATE	**DELIVERY MODE**
11/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/910,388	KUNZ, LAWRENCE L.	
	Examiner	Art Unit	
	Hope A. Robinson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50 and 52-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50 and 52-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *2/29/01* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/29/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Application Status

1. Applicant's response to the Office Action mailed March 30, 2007 on August 29, 2007, is acknowledged.

Claim Disposition

2. Claims 56-59 have been added. Claims 50 and 52-59 are pending and are under examination.

Information Disclosure Statement

3. The Information Disclosure Statements filed on August 29, 2007 have been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

Maintained-Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 50 and 52-59 are rejected under 35 U.S.C. ə 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims recite added material, which is not supported by the original disclosure. Claim 50 (and dependent claims 52-59) recite "activity without killing the cell" and "free therapeutic agent is not heparin..." and no support was found in the instant specification for this language or at the pages in specification pointed to by applicant. It is suggested that the new matter is deleted from the specification and claims. Therefore, the specification lacks adequate written description.

In addition, the claims are directed to a method for reducing restenosis comprising administering a free therapeutic agent that inhibits vascular smooth muscle cell migration and the claims read on a genus of inhibitors not adequately described in the instant specification (see for example claim 58). On page 5 of the instant specification therapeutic agents such as taxol, or taxotere, or protein kinases are disclosed, however, the claims broadly reads on any "therapeutic agents" which encompasses inhibitors not contemplated or described by the claimed invention. The claims encompass a large genus of inhibitors not adequately described. Thus, one of skill in the art would be unable to predict the structure of other members of this genus by virtue of the instant disclosure. The specification fails to provide any additional representative species of the claimed genus, to show that applicant was in possession

of the claimed genus. A representative number of species means that the species, which are adequately described, are representative of the entire genus. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

Further, *Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir.1991)*, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. *See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993).* Therefore, for all these reasons the specification lacks adequate written

description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

5. Claims 50 and 52-59 are rejected under 35 U.S.C. ə 112, first paragraph, scope of enablement, because the specification, while being enabling for a method of reducing restenosis by administering taxol, does not reasonably provide enablement for any therapeutic agent/inhibitor employed by the method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: Quantity of Experimentation Necessary; Amount of direction or guidance presented; Presence or absence of working examples; Nature of the Invention; State of the prior art and Relative skill of those in the art; Predictability or unpredictability of the art and Breadth of the claims (see *In re Wands, 858 F.2d at 737, 8 USPQ2d at1404 (Fed. Cir. 1988)*. The factors most relevant to the instant invention are discussed below.

The amount of experimentation required to practice the claimed invention is undue as the claims encompass a genus of inhibitors not supported by the instant specification. The specification on page 5 provides a discussion of therapeutic agents to be used as inhibitors of vascular smooth muscle cell migration such as taxol. Taxol is know in the art to inhibit neointimal smooth muscle cell accumulation after angioplasty

(see Sollott et al., The Journal of Clinical Investigation, vol. 95, April 1995, pages 1869-1876), however, the claimed invention is not limited to taxol as it encompasses any therapeutic agent. It is noted that claim 50 is amended to recite a negative proviso with respect to the therapeutic agent, however, no support was found in the instant specification for this language and further, this language does not per se provide a listing of what is considered to be a "free therapeutic agent", just what it is not. The specification also discloses therapeutic agents such as protein kinases and taxol analogs and provides examples such as "staurosporin and taxotere, however, the claims are not limited to the inhibitors disclosed. Moreover, claim 58 is directed to any derivative thereof or analog thereof, absent guidance as to what the structures look like, to provide correlation between structure and function. Undue experimentation would be required to test all possible inhibitors to determine if they have the desired activity.

No guidance is presented with regard to other members of the genus encompassed in the claims. One of skill in the art would be unable to predict the structure of other members of this genus by virtue of the instant disclosure.

The working examples provided do not rectify the missing information in the instant specification pertaining to the claimed inhibitors. The nature and properties of this claim is difficult to ascertain from the examples provided as one of skill in the art would have to engage in undue experimentation to construct all inhibitors of the claimed invention and examine the same for function.

The issue in this case is the breath of the claims in light of the predictability of the art as determined by the number of working examples, the skill level artisan and the

guidance presented in the instant specification and the prior art of record. This make and test position is inconsistent with the decisions of *In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)* where it is stated that "...scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art...". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).*

Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claims, the lack of guidance and working examples provided in the specification and the high degree of unpredictability as evidenced by the state of the prior art, attempting to construct and test all possible inhibitors of the claimed invention would constitute undue experimentation. Making and testing the infinite number of possible inhibitors to find one that functions as described is undue experimentation. Therefore, applicants have not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner that reasonably correlates with the scope of the claims, to be considered enabling.

Response to Applicant's Arguments:

6. Applicant's arguments have been fully considered and the art rejections are withdrawn based on the amendments made to claim 50, however, once the new matter is deleted from the claim, the art rejections could be reinstated if applicable. Note that a new rejection has been made under 35 USC 112, first paragraph based on lack of support for the recited language as indicated above. In addition, the previous rejections under 35 USC 112, first paragraph with respect to written description and enablement remains because the claims is directed to a genus not adequately described (see for example claim 58 with the recited "derivative or analog thereof. Applicant's arguments are were not persuasive with respect to the amendments made to claim 50 obviating the rejections of record under 35 USC 112, first paragraph. The claims remain drawn to a genus of inhibitors as the negative proviso has no support in the instant specification and does not define what the agent is, just what it is not. Further, claim 58 for example is directed to any analog or derivative. Thus, the rejection remains.

Conclusion

7. No claims are presently allowable.

8. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP ɔ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS HR 11/10/07

Primary Examiner

HOPE ROBINSON
PRIMARY EXAMINER